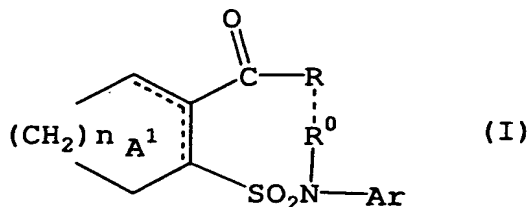


WHAT IS CLAIMED IS

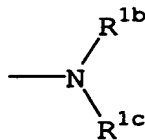
1. An agent for the prophylaxis or treatment of severe sepsis,
which comprises a cycloalkene compound as an active
5 ingredient.

2. An agent for the prophylaxis or treatment of severe sepsis,
which comprises a compound represented by the formula (I):



10 wherein

R represents an aliphatic hydrocarbon group optionally
having substituents, an aromatic hydrocarbon group
optionally having substituents, a heterocyclic group
optionally having substituents, a group represented by
15 the formula: -OR¹ wherein R¹ represents a hydrogen atom
or an aliphatic hydrocarbon group optionally having
substituents, or a group represented by the formula:



wherein

20 R^{1b} and R^{1c}

are the same or different and each represents a
hydrogen atom or an aliphatic hydrocarbon group
optionally having substituents,

R⁰ represents a hydrogen atom or an aliphatic hydrocarbon
25 group, or R and R⁰ in combination form a bond,

ring A¹ represents a cycloalkene optionally substituted by 1
to 4 substituents selected from the group consisting
of

(1) an aliphatic hydrocarbon group optionally having substituents,

(2) an aromatic hydrocarbon group optionally having substituents,

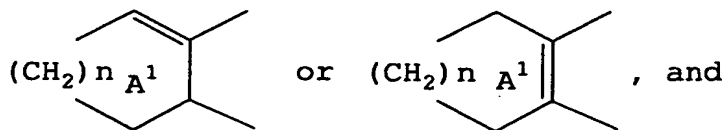
5 (3) a group represented by the formula: $-OR^{11}$ wherein R^{11} represents a hydrogen atom or an aliphatic hydrocarbon group optionally having substituents and
(4) a halogen atom,

Ar represents an aromatic hydrocarbon group optionally
10 having substituents,

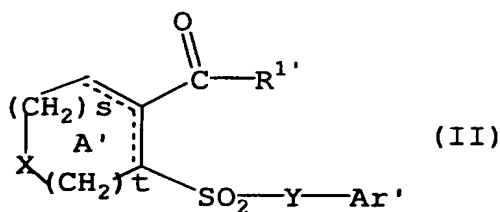
a group represented by the formula:



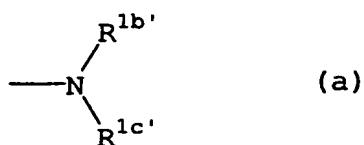
represents a group represented by the formula:



15 n represents an integer of 1 to 4,
or a salt thereof or a prodrug thereof, or a compound
represented by the formula (II):



wherein $R^{1'}$ represents an aliphatic hydrocarbon group
optionally having substituents, an aromatic hydrocarbon group
20 optionally having substituents, a heterocyclic group
optionally having substituents, a group represented by the
formula: $-OR^{1a'}$ wherein $R^{1a'}$ represents a hydrogen atom or an
aliphatic hydrocarbon group optionally having substituents, or
a group represented by the formula:



wherein $\text{R}^{1b'}$ and $\text{R}^{1c'}$ are the same or different and each represents a hydrogen atom or an aliphatic hydrocarbon group optionally having substituents,

5 X represents a methylene group, NH, a sulfur atom or an oxygen atom,

Y represents a methylene group optionally having substituents or NH optionally having substituents,

ring A' represents a 5- to 8-membered ring optionally having 1

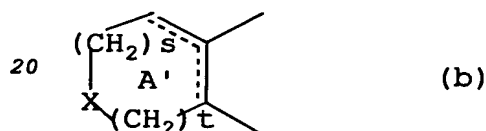
10 to 4 substituents selected from the group consisting of (1) an aliphatic hydrocarbon group optionally having substituents,

(2) an aromatic hydrocarbon group optionally having substituents, (3) a group represented by the formula: $-\text{OR}^{2'}$ wherein $\text{R}^{2'}$ represents a hydrogen atom or an aliphatic

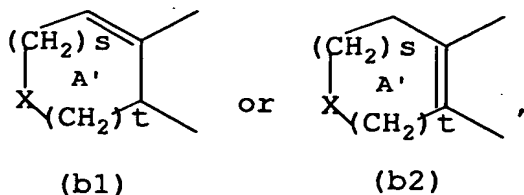
15 hydrocarbon group optionally having substituents and (4) a halogen atom,

Ar' represents an aromatic hydrocarbon group optionally having substituents,

a group represented by the formula:



represents a group represented by the formula:



s represents an integer of 0 to 2,

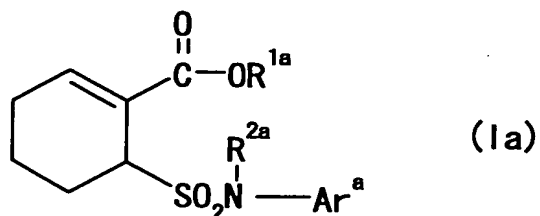
t represents an integer of 1 to 3, and

25 the total of s and t is not more than 4;

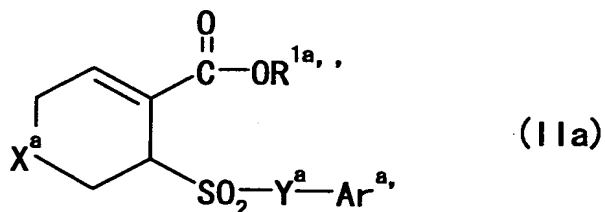
provided that when X is a methylene group, Y represents a

methylene group optionally having substituents, or a salt thereof or a prodrug thereof.

3. The agent of claim 2, wherein the formula (I) is the
5 formula (Ia):



wherein R^{1a} represents a C₁₋₆ alkyl, R^{2a} represents a hydrogen atom or a C₁₋₆ alkyl and Ar^a represents a phenyl group substituted by 1 or 2 halogen atoms, and the formula (II) is
10 the formula (IIa):



wherein R^{1a''} represents a C₁₋₆ alkyl, X^a represents a methylene group or an oxygen atom, Y^a represents a methylene group or -NH- and Ar^{a'} represents a phenyl group optionally having 1 or 2
15 substituents selected from a halogen atom and a C₁₋₆ alkoxy group.

4. The agent of claim 2, further comprising at least one kind of drug selected from the group consisting of antibacterial
20 agent, antifungal agent, non-steroidal antiinflammatory drug, steroid and anticoagulant.

5. A method for the prophylaxis or treatment of severe sepsis, which comprises administration of an effective amount of a
25 compound represented by the formula (I) or the formula (II) or

a salt thereof or a prodrug thereof described in claim 2 to a mammal.

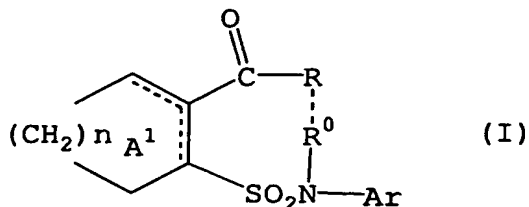
6. Use of a compound represented by the formula (I) or the
5 formula (II) or a salt thereof or a prodrug thereof described
in claim 2 for the production of an agent for the prophylaxis
or treatment of severe sepsis.

7. A TLR signal inhibitor comprising a non-peptide compound as
10 an active ingredient.

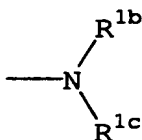
8. The agent of claim 7, wherein the non-peptide compound is a
non-peptide compound having a molecular weight of not more
than about 1000.

15

9. The agent of claim 8, wherein the non-peptide compound is a
compound represented by the formula (I):



wherein R represents an aliphatic hydrocarbon group optionally
20 having substituents, an aromatic hydrocarbon group optionally
having substituents, a heterocyclic group optionally having
substituents, a group represented by the formula: $-OR^1$ wherein
 R^1 represents a hydrogen atom or an aliphatic hydrocarbon group
optionally having substituents, or a group represented by the
25 formula:



wherein R^{1b} and R^{1c} are the same or different and each
represents a hydrogen atom or an aliphatic hydrocarbon group

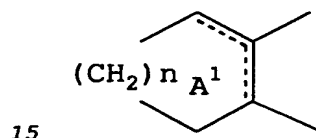
optionally having substituents,

R^0 represents a hydrogen atom or an aliphatic hydrocarbon group, or R and R^0 in combination form a bond,

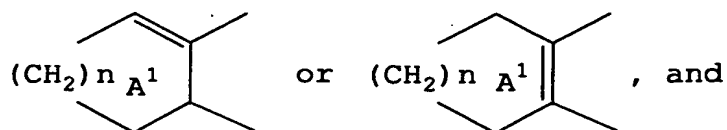
ring A^1 represents a cycloalkene optionally substituted by 1 to
5 4 substituents selected from the group consisting of (1) an aliphatic hydrocarbon group optionally having substituents, (2) an aromatic hydrocarbon group optionally having substituents, (3) a group represented by the formula: $-OR^{11}$ wherein R^{11} represents a hydrogen atom or an aliphatic
10 hydrocarbon group optionally having substituents and (4) a halogen atom,

Ar represents an aromatic hydrocarbon group optionally having substituents,

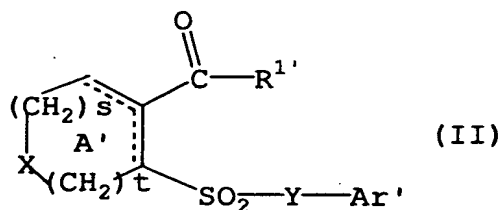
a group represented by the formula:



represents a group represented by the formula:

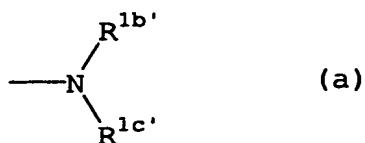


n represents an integer of 1 to 4, or a salt thereof or a
20 prodrug thereof, or, a compound represented by the formula (II):

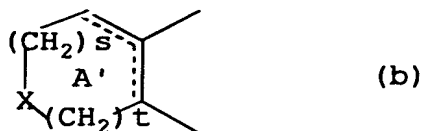


wherein $R^{1'}$ represents an aliphatic hydrocarbon group optionally having substituents, an aromatic hydrocarbon group optionally having substituents, a heterocyclic group
25 optionally having substituents, a group represented by the

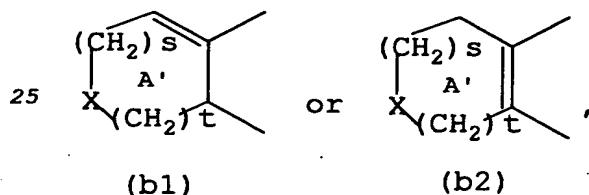
formula: $-OR^{1a'}$ wherein $R^{1a'}$ represents a hydrogen atom or an aliphatic hydrocarbon group optionally having substituents, or a group represented by the formula:



- 5 wherein $R^{1b'}$ and $R^{1c'}$ are the same or different and each represents a hydrogen atom or an aliphatic hydrocarbon group optionally having substituents,
 X represents a methylene group, NH, sulfur atom or oxygen atom,
 10 Y represents a methylene group optionally having substituents or NH optionally having substituents,
 ring A' represents a 5 to 8-membered ring optionally having 1 to 4 substituents selected from the group consisting of (1) an aliphatic hydrocarbon group optionally having substituents,
 15 (2) an aromatic hydrocarbon group optionally having substituents, (3) a group represented by the formula: $-OR^{2'}$ wherein $R^{2'}$ represents a hydrogen atom or an aliphatic hydrocarbon group optionally having substituents and (4) a halogen atom,
 20 Ar' represents an aromatic hydrocarbon group optionally having substituents,
 a group represented by the formula:



represents a group represented by the formula:



s represents an integer of 0 to 2,

t represents an integer of 1 to 3,
the total of s and t is not more than 4;
provided that when X is a methylene group, Y represents a
methylene group optionally having substituents, or a salt
5 thereof or a prodrug thereof.

10. The agent of claim 7, wherein TLR is TLR4.

11. An agent for the prophylaxis or treatment of a disease
10 caused by a change in a TLR signal, which comprises the agent
of claim 7.

12. The agent of claim 11, wherein the disease caused by the
changes in the TLR signal is organ dysfunction.

15

13. The agent of claim 12, wherein the organ is an organ of
central nervous system, circulatory system, respiratory
system, bone and joint system, digestive system or renal and
urinary system.

20

14. A method for the inhibition of TLR signal, which comprises
administration of an effective amount of a non-peptide
compound to a mammal.

25 15. A method for the prophylaxis or treatment of a disease
caused by a change in a TLR signal, which comprises
administration of an effective amount of a non-peptide
compound to a mammal.

30 16. Use of a non-peptide compound for the production of a TLR
signal inhibitor.

17. Use of a non-peptide compound for the production of an

agent for the prophylaxis or treatment of a disease caused by a change in a TLR signal.

18. An agent for the prophylaxis or treatment of organ
5 dysfunction, which comprises a TLR signal inhibitory substance.

19. The agent of claim 18, wherein the organ is an organ of
central nervous system, circulatory system, respiratory
10 system, bone and joint system, digestive system or renal and
urinary system.

20. A method for the prophylaxis or treatment of severe sepsis
or organ dysfunction, which comprises inhibition of TLR
15 signal.